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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,621	09/18/2000	Kristophes S. Buchanan	XY-SONC-USNP	7362

7590

05/07/2003

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/622,621

Applicant(s)

BUCHANAN ET AL.

Examiner

Maureen M. Wallenhorst

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-109 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 34-37, 41-44, 50, 51, 53, 68, 69, 105 and 106 is/are allowed.
- 6) ☒ Claim(s) 6-33, 38-40, 45-49, 52, 54-67, 70-104 and 107-109 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. Applicants are requested to provide the abstract from the corresponding PCT application on a separate sheet.

2. Claims 6-33, 38-40, 45-49, 52, 54-62, 64-67, 70-104 and 108-109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite since it is not clear what portion of the portable oscillating device the cup surface belongs to or is connected to. Is the cup surface a part of the receptacle recited in claim 3?

On line 4 of claim 11, the phrase "said portable surface" lacks antecedent basis.

Claim 12 is indefinite since it is not clear how the joining element is structurally connected to the rest of the portable oscillating device.

On line 3 of claim 19, the phrase "said mechanically isolated receptacle" lacks antecedent basis since claim 19 depends from claim 1, and claim 1 fails to positively recite the mechanically isolated receptacle. On line 4 of claim 19, the phrase "said portable surface" lacks antecedent basis.

On line 2 of claim 21, the phrase "said activation circuit" lacks antecedent basis since claim 21 depends from claim 19, not claim 20. On line 3 of claim 21, the word "which" should be deleted so that the claim makes proper sense.

The preamble of claim 23 should be changed to –The drop flow cytometer system of claim 22—since claim 23 depends from claim 22, and claim 22 recites a drop flow cytometer system. This same change should also be made in claim 24.

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At the end of claim 24, the word “surface” should be deleted so that the claim makes proper sense. This same change should also be made in claims 27, 30 and 33.

The preamble of claim 26 should be changed to –The drop flow cytometer system of claim 25—since claim 26 depends from claim 25, and claim 25 recites a drop flow cytometer system. This same change should also be made in claim 27.

The preamble of claim 29 should be changed to –The drop flow cytometer system of claim 28—since claim 29 depends from claim 28, and claim 28 recites a drop flow cytometer system. This same change should also be made in claim 30.

The preamble of claim 32 should be changed to –The drop flow cytometer system of claim 31—since claim 32 depends from claim 31, and claim 31 recites a drop flow cytometer system. This same change should also be made in claim 33.

On line 2 of claim 38, the word “element” should be deleted so as to use the same terminology as used in claim 37. This same change should also be made on line 2 of claims 39-40.

At the end of claim 45, the word “surface” should be deleted.

In claim 46, the phrases “said oscillation parameter selector” and “said oscillation parameters” lack antecedent basis. See this same problem in claims 47-49.

On line 2 of claims 47-49, the word “element” should be deleted so as to be consistent with the terminology used in claim 46.

On line 3 of claim 52, the word “changes” should be deleted so as to make proper sense.

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Claim 54 is indefinite since it is not clear whether the fluidic oscillation coupling element serves to couple the mechanical oscillations created by the energy converter to the flow cytometer nozzle exterior surface.

Claim 55 is indefinite since it should depend from claim 54 in order for the fluidic oscillation coupling element in part d. to make proper sense.

On the last line of claim 62, the word “system” should be deleted.

Claim 64 is indefinite since it should depend from claim 63 in order for the oscillation variation system in part d. to make proper sense. In part e. of claim 64, the phrase “said flow cytometer nozzle exterior surface” lacks antecedent basis since if claim 64 properly depends from claim 63, claim 63 fails to positively recite the flow cytometer nozzle exterior surface.

Claim 65 is indefinite since it should depend from claim 64 in order for the phrase “said nozzle body” to have proper antecedent basis. On line 2 of claim 65, the word “selection” should be deleted. This same change should also be made on line 2 of claims 66 and 67.

In claim 70, the phrases “said receptacle”, “said mechanical oscillations” and “said flow cytometry nozzle” lack antecedent basis since claims 68-69 do not positively recite any of these elements.

On line 2 of claim 71, the phrase “said portable surface” lacks antecedent basis.

On line 3 of claim 73, the phrase “said cup surface” should be changed to – said surface--

This same change should be made on line 3 of claims 74 and 75.

On line 6 of claim 78, the phrase “said surface” is indefinite since it is not clear what surface this is referring to, i.e. the exterior surface of the flow cytometer apparatus?

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In claim 79, the phrases “said mechanical oscillations”, “said energy converter” and “said parameter” lack antecedent basis.

Claim 88 is indefinite since it is not clear how the de-bubbling energy converter serves to dislocate gas bubbles from within the flow cytometry apparatus since the energy converter has not been positively recited as being connected in any way to the flow cytometry apparatus. How are the flow cytometry apparatus and the energy converter structurally related to one another so as to achieve the recited function?

On line 1 of claim 89, the preamble of the claim should be changed to recite –A method of flow cytometry comprising the steps of:--. Claim 89 is indefinite since it is not clear that the oscillations created in the vicinity of the flow cytometry apparatus are the mechanical oscillations outputted by the energy converter. It is not clear how the source of energy, energy converter, etc. are structurally related to the exterior surface of the flow cytometry apparatus in order to achieve the recited functions.

On line 3 of claim 93, the phrase “said interior surface” lacks antecedent basis.

In claim 95, the phrases “said oscillation coupling element” and “said portable member” lack antecedent basis these components are not recited in any of the previous claims depending from independent claim 89.

On line 3 of claim 96, the phrase “said parameter” lacks antecedent basis.

In claim 97, the phrase “said portable member” lacks antecedent basis. See this same problem on line 2 of claims 98, 100 and 102.

Claim 101 is indefinite since it recites the exact same limitation as claim 99, and both claims 101 and 99 depend from claim 96.

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Part d. of claim 108 is indefinite since it is not clear what the phrase “in the vicinity of said flow cytometry apparatus” means. Does this mean oscillations are created on the exterior, the interior or both the exterior and interior of the flow cytometry apparatus?

Applicants are requested to review the currently pending claims in depth to ensure that all claims depend from the proper independent claim, and that all recited features of the invention in the claims have proper antecedent basis.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 63 and 107-109 are rejected under 35 U.S.C. 102(b) as being anticipated by Van den Engh (US Patent no. 5,602,039, submitted in the Information Disclosure Statement filed on August 18, 2000).

Van den Engh teaches of a flow cytometer jet system 1 that comprises a nozzle system 42 which acts to introduce a flow of a substance within a sheath fluid. A substance introduction

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port 9 is included in the nozzle volume 3 so that a substance may be introduced into the sheath fluid. The sheath fluid with its entrained substance is focused so that single cells are emitted from the nozzle exit 6 into a free fall area 7. By allowing the sheath fluid to exit from the nozzle volume 3, a jet 12 is created. This jet occurs within free fall area 7 where it is analyzed. An oscillator 10 serves to initiate vibrations within the jet 12 so that its oscillations act to form droplets 13 from the sheath fluid. Each of the droplets are analyzed, and a sorting equipment 16 is included in the apparatus to differentially charge each droplet containing a substance of interest, and deflect them electrostatically. A controller 34 is connected to the oscillator 10, and serves to control the location at which the droplet separation point 69 occurs. This is because the oscillator 10 acts to cause droplets 13. The oscillator 10 is controlled by an alternating voltage source 22, which acts as an oscillator drive. When this oscillator drive applies an alternating voltage to the oscillator 10, oscillations occur within the sheath fluid, which causes droplets 13 to form. The controller 34 may act to vary the amplitude supplied from the alternating voltage source 22 to oscillator 10. Therefore, the amplitude of the pressure wave within the sheath fluid may be varied in a manner which adjusts the location at which the droplet separation point 69 occurs.

The teaching of Van den Engh anticipates claim 63 since the alternating voltage source 22 acts as an energy source, the controller 34 serves as an energy transfer element, and the oscillator 10 serves as an energy converter connected to the energy transfer element to output mechanical oscillations. The changing amplitude of the energy supplied from the alternating voltage source 22 to the oscillator serves as an oscillation variation system for changing an oscillation parameter, i.e. the amplitude of the supplied energy.

The teaching of Van den Engh anticipates the method recited in claim 107 since two different oscillation modes can be created with the apparatus disclosed by Van den Engh. The second oscillation mode would be a different oscillation value from the oscillation value in the first oscillation mode, provided by the oscillator as a result of a changed energy amplitude supplied by the alternating voltage source 22. Claim 107 does not recite that the sheath fluid is not responsive to the second oscillation mode.

Claim 108 is anticipated by the teaching of Van den Engh since oscillations are created in the vicinity of the flow cytometry apparatus disclosed therein, i.e. in the sheath fluid located in the nozzle volume. In addition, the oscillations are swept through a range of an oscillation parameter. The oscillation parameter would be the amplitude of the pressure wave or energy supplied by the alternating voltage source 22, which is changed to different values to create different droplet separation points.

6. Claims 63 and 108-109 are rejected under 35 U.S.C. 102(b) as being anticipated by Auer (US Patent no. 4,487,320).

Auer teaches of a particle separator for sorting particles suspended in a liquid. The apparatus includes a flow chamber 12 into which a sheath fluid of saline is introduced under pressure and exits through a small orifice 14 to form a liquid jet stream 16. A sample is introduced into the flow chamber 12 through a tube 18. The flow chamber is mounted to and supported by a piezo-electric crystal assembly 24 which vibrates the chamber 12 at a high frequency. These vibrations impart small disturbances on the jet 16, which causes well defined droplets 28 to form at a breakoff point 26. The size of the disturbance is proportional to the amplitude of the signal voltage applied to the crystal 24. The piezo-electric crystal is driven by a

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power amplifier 30, which derives its signal from a frequency generator 32 through a variable potentiometer 34. The potentiometer is used to vary the amplitude of the signal applied to crystal 24, and therefore, vary the breakoff point 26.

The teaching of Auer ('320) anticipates the oscillation system recited in instant claim 63 since the frequency generator 32 serves as an energy source, the power amplifier 30 serves as an energy transfer element, and the crystal 24 serves as an energy converter connected to the transfer element which outputs mechanical oscillations. The changing amplitude of the energy supplied from the frequency generator 32 through the potentiometer 34 to the crystal 24 serves as an oscillation variation system for changing an oscillation parameter, i.e. the amplitude of the supplied energy.

Claim 108 is anticipated by the teaching of Auer ('320) since oscillations are created in the vicinity of the flow chamber 12 disclosed therein. In addition, the oscillations are swept through a range of an oscillation parameter. The oscillation parameter would be the amplitude of the pressure wave or energy supplied by the frequency generator 32, which is changed to different values by the potentiometer 34 to create different droplet separation points.

7. Claims 1-5, 34-37, 41-44, 50-51, 53, 68-69 and 105-106 are allowable as is over the prior art of record since the prior art of record fails to teach or fairly suggest the use of a portable oscillating device for coupling mechanical oscillations to the exterior of a flow cytometer nozzle in order to clean the nozzle and prevent clogging of the nozzle, and a flow cytometer system having an oscillation system responsive to both a first and second driver system having different oscillation parameters in order to create mechanical oscillations coupled to the exterior surface of a flow cytometer nozzle.

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8. Claims 54, 88 and 89 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action for the same reasons as given above.

9. Claims 6-33, 38-40, 45-49, 52, 55-62, 64-67, 70-87 and 90-104 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims for the same reasons as given above.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Gross et al (EP 461,618), Van den Engh (WO 96/12171), Auer (US Patent no. 4,981,580), who all teach of different types of flow cytometer droplet formation systems.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 703-308-3912. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

May 4, 2003

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP ~~100~~ 1700